



IAP7 Rec'd PCT/PTO 26 JAN 2006

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q90374

Young Min KIM, et al.

Appln. No.: 10/551,764

Group Art Unit: Unassigned

Confirmation No.: Unknown

Examiner: Unassigned

Filed: October 3, 2005

For: PEG-PHYSIOLOGICALLY ACTIVE POLYPEPTIDE HOMODIMER COMPLEX
HAVING PROLONGED IN VIVO HALF-LIFE AND PROCESS FOR THE
PREPARATION THEREOF

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

1. Brian C. Cunningham et al., "Rational design of receptor-specific variants of human growth hormone", *Proc. Natl. Acad. Sci. USA*, Vol. 88, April 1991, pp. 3407-3411.
2. Dieter Haffner et al., "Metabolic Clearance of Recombinant Human Growth Hormone in Health and Chronic Renal Failure", *J. Clin. Invest.*, Vol. 93, March 1994, pp. 1163-1171.
3. Ross Clark et al., "Long-acting Growth Hormones Produced by Conjugation with Polyethylene Glycol", *The Journal of Biological Chemistry*, Vol. 271, No. 36, Sept. 6, 1996, pp. 21969-21977.

REC'D 7/23/06 7:00 AM 2006
USPTO 2006

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INFORMATION DISCLOSURE STATEMENT

4. Yoshinobu Fukumori et al., "Coating of Pharmaceutical Powders by Fluidized Bed Process. III. Aqueous Coating with Ethyl Acrylate-Methyl Methacrylate-2-Hydroxyethyl Methacrylate Copolymer and the Dissolution Properties of the Products", *Chem. Pharm. Bull.*, Vol. 36, 1988, pp. 3070-3078.
5. Steven M. Chamow et al., "Modification of CD4 Immunoadeshin with Monomethoxypoly(ethylene glycol) Aldehyde via Reductive Alkylation", *Bioconjugate Chem.*, Vol. 5, 1994, pp. 133-140.
6. Liew-Cheng Teh & George E. Chapman, "Determination of the Effect of Acetylation of Specific Lysine Residues in Human Growth Hormone on its Affinity for Somatogenic Receptors by an Affinity Selection Technique", *Biochemical and Biophysical Research Communications*, Vol. 150, No. 1, January 15, 1988, pp. 391-398.
7. A. L. Baldwin et al., "Bioactivity and immunoactivity of growth hormone during dynamic testing of patients with acromegaly", *Acta Endocrinologica (Copenh)*, Vol. 119, 1988, pp. 326-332.
8. M. Bozzola et al., "Evaluation of growth hormone bioactivity using the Nb₂ cell bioassay in children with growth disorders", *J. Endocrinol. Invest.*, Vol. 21, 1998, pp. 765-770.
9. James A. Wells et al., "The Molecular Basis for Growth Hormone-Receptor Interactions", *Recent Progress in Hormone Research*, Vol. 48, 1993, pp. 253-275.

One copy of each of the listed documents is submitted herewith.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not

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INFORMATION DISCLOSURE STATEMENT

waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,



Sunhee Lee
Registration No. 53,892

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

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Date: January 26, 2006

Substitute for Form 1449 A & B/PTO

Complete if Known

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

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Application Number	10/551,764
Confirmation Number	Unknown
Filing Date	October 03, 2005
First Named Inventor	Young Min KIM
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	Q90374

Sheet

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of

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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code ² (if known)		
		US			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)			

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation ⁶
		Brian C. Cunningham et al., "Rational design of receptor-specific variants of human growth hormone", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 88, April 1991, pp. 3407-3411	
		Dieter Haffner et al., "Metabolic Clearance of Recombinant Human Growth Hormone in Health and Chronic Renal Failure", <i>J. Clin. Invest.</i> , Vol. 93, March 1994, pp. 1163-1171	
		Ross Clark et al., "Long-acting Growth Hormones Produced by Conjugation with Polyethylene Glycol", <i>The Journal of Biological Chemistry</i> , Vol. 271, No. 36, Sept. 6, 1996, pp. 21969-21977	
		Yoshinobu Fukumori et al., "Coating of Pharmaceutical Powders by Fluidized Bed Process. III. Aqueous Coating with Ethyl Acrylate-Methyl Methacrylate-2-Hydroxy-ethyl Methacrylate Copolymer and the Dissolution Properties of the Products", <i>Chem. Pharm. Bull.</i> , Vol. 36, 1988, pp. 3070-3078	
		Steven M. Chamow et al., "Modification of CD4 Immunoaodeshin with Monometh-oxypoly(ethylene glycol) Aldehyde via Reductive Alkylation", <i>Bioconjugate Chem.</i> , Vol. 5, 1994, pp. 133-140	
		Liew-Cheng The & George E. Chapman, "Determination of the Effect of Acetylation of Specific Lysine Residues in Human Growth Hormone on its Affinity for Somatogenic Receptors by an Affinity Selection Technique", <i>Biochemical and Biophysical Research Communications</i> , Vol. 150, No. 1, January 15, 1988, pp. 391-398	
		A. L. Baldwin et al., "Bioactivity and immunoactivity of growth hormone during dynamic testing of patients with acromegaly", <i>Acta Endocrinologica (Copenh)</i> , Vol. 119, 1988, pp. 326-332	
		M. Bozzola et al., "Evaluation of growth hormone bioactivity using the Nb ₂ cell bioassay in children with growth disorders", <i>J. Endocrinol. Invest.</i> , Vol. 21, 1998, pp. 765-770	
		James A. Wells et al., "The Molecular Basis for Growth Hormone-Receptor Interactions", <i>Recent Progress in Hormone Research</i> , Vol. 48, 1993, pp. 253-275	

Examiner Signature	Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov. MPEP 901.04 or in the comment box of this document. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to indicate here if English language Translation is attached.